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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,610	02/03/2006	Jiri Jan Krepinsky	14096.55USWO	7658
23552	7590	06/18/2007		
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER MARTIN, PAUL C	
			ART UNIT	PAPER NUMBER
			1657	
			MAIL DATE	DELIVERY MODE
			06/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/530,610

Applicant(s)

KREPINSKY ET AL.

Examiner

Paul C. Martin

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-9,12-14,17-19 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9,12-14,17-19 and 23-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-3, 5-9, 12-14, 17-19 and 23-28 are pending in this application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The objection to Claim 7 has been withdrawn due to the Applicant's amendments to the claims filed 4/4/07.

The rejection of Claims 1, 25 and 26 under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn due to the Applicant's amendments to the claims filed 4/4/07.

The rejection of Claim 1 under 35 U.S.C. § 102(b) as being anticipated by Shamsuddin (US 5,348,860) has been withdrawn due to the Applicant's amendments to the claims filed 4/4/07.

The rejection of Claims 1-3, 5-8, 12, 14, 17, 23, 24 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Shamsuddin (US 5,348,860) is maintained for reasons of record set forth in the Action mailed 12/18/06.

The rejection of Claims 1-3, 5-8, 12, 14, 17, 19, 23, 24 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Shamsuddin (US 5,348,860) in view of Sauter *et al.* (1999) is maintained for reasons of record set forth in the Action mailed 12/18/06.

The rejection of Claims 1-3, 5-9, 12-14, 17, 18 and 24-28 under 35 U.S.C. § 103(a) as being unpatentable over Shamsuddin (US 5,348,860) in view of Krepinsky *et al.* (US 6,187,591 B1) is maintained for reasons of record set forth in the Action mailed 12/18/06.

### ***Response to Arguments***

Applicant's arguments filed 03/19/07 have been fully considered but they are not persuasive.

The Applicant seems to argue that the method as practiced by Shamsuddin does not teach the detection of an aldehyde marker, the detection of breast cancer, lack of pre-washing step and that the methods are significantly different (Remarks, Pg. 7-9).

Applicant's arguments are not found to be persuasive for the following reasons, as discussed in the prior action, the method of Shamsuddin teaches a method for screening for a cancerous or precancerous condition in discharge from the breast of a human female comprising the steps of; obtaining a sample from the subject; depositing the sample on a water insoluble support, treating the sample with an aldehyde detecting Schiff's reagent and detecting a magenta coloration which is indicative of a cancerous or precancerous condition. It is inherent in the method of Shamsuddin that aldehyde markers are detected, and the use of Schiff's reagent to this purpose is clearly taught (Column 6, Lines 24-29). As the reference comprises each and every method step (less the lack of pre-washing, which is addressed in the 103(a) rejection) it is deemed by the Examiner that the Shamsuddin reference obviates the instantly claimed invention. That the Shamsuddin reference generates the aldehyde marker through enzymatic catalysis does not distinguish the two references as each and every method step of the instant invention uses a method comprising certain method steps, but not limited to those method steps.

The Applicant argues that the Examiner has provided no support for the position that a person skilled in the art would be so motivated to obtain a sample of breast fluid of one or both non-lactating breasts of a subject, treating the sample with a Schiff's reagent without any pre-washing and that this less invasive and simpler method would work. Applicant argues that if this was obvious this procedure would be the norm prior to the Applicant's instant invention (Remarks, Pg. 10, Lines 5-10).

The Applicant's arguments are not found to be persuasive because support for the Examiner's position came from scientific reasoning, and evidentiary support is not absolutely necessary in making an obviousness rejection. Applicant's suggestion that this was not obvious because no one had thought to do this prior to the Applicant's invention does not make the invention non-obvious.

The Applicant argues that it would not be obvious to a person skilled in the art why specimens of Nipple aspirate fluid from breast cancer would provide purple-magenta coloration without first being previously treated with galactose oxidase leading to negative results (Remarks, Pg. 10, Lines 16-23).

This is not found to be persuasive because it is though combination of the two references, i.e., the use of nipple aspirate fluid in screening for aldehyde markers and detecting a cancerous or precancerous condition as taught by Shamsuddin and Krepinsky which teaches the detection of aldehydes using Schiff's reagent without the step of adding galactose oxidase or catalase that the limitations of the instant invention are met.

The Applicant argues that one of ordinary skill in the art would not expect that after treatment with a Schiff reagent, the reaction between an aldehyde marker and the Schiff reagent would form an insoluble product which would adhere to polyester fabric (Remarks, Pg. 11, Lines 5-9).

This is not found to be persuasive because Krepinsky clearly teaches the formation of a purple coloration from reaction of Schiff's reagent with long chain aliphatic fatty aldehydes (Column 7, Lines 11-19), whether or not there is adherence or retention is not instantly claimed.

Applicant argues that the present inventors have discovered that the plasmalogen markers of the present invention behave differently from those in the colorectal cancer of Krepinsky *et al.* and by implication this indicates that they may be of different structure and have different properties (Remarks, Pg. 11, Lines 10-15).

This is not found to be persuasive because evidence indicating the alleged differences has not been provided, that there *may* be a difference does not indicate that such a difference exists.

Applicant argues that there are no plasmalogens from which water soluble, low molecular weight aldehydes are derived (Remarks, Pg. 11, Lines 16-20).

This is not found to be persuasive because of the teachings of Krepinsky *et al.* which clearly teaches that mucus bound aldehydes are released from acid-sensitive plasmalogens under acidic conditions and that low molecular weight aliphatic aldehydes are present in the mucus as well (Column 6, Lines 45-49 and 64-67).

The Applicant argues that pre-washing of the sample prior to aldehyde detection is detrimental to the procedure (Remarks, Pg. 11, Lines 25-31 and Pg. 12, Lines 1-2).

This is not found to be persuasive because as discussed in the prior action, the steps of adding or removing washing steps would be considered matters of routine optimization and judicious selection.

The Applicant argues that the combination of Shamsuddin and Sauter *et al.* does not contain all of the limitations of the claimed invention, and that Sauter did not conclude that a simple application of Schiff's reagent to nipple aspirate could reveal aldehyde cancer markers (Pg. 12, Lines 5-13).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, this is not found to be persuasive because Sauter *et al.* was only brought in for its teachings of screening nipple aspirate for candidate biomarkers associated with cancer risk.



The teachings of Sauter *et al.* as well as the obviousness and motivations to combine were discussed in the prior action. Applicant alleges Sauter *et al.* did not conclude that a simple application of Schiff's base to nipple aspirate could reveal aldehyde cancer markers however, support for this has not been provided or found in the reference.

### ***Conclusion***

No Claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax-phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin  
Examiner  
Art Unit 1657

6/5/07

A handwritten signature in black ink, appearing to read 'Jon Weber', is written over the printed name and title.

**Jon Weber**  
**Supervisory Patent Examiner**